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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/577,506	11/30/2006	Shi Du Yan	68547-PCT-US/JPW/CH	9792

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EXAMINER	
GUCKER, STEPHEN	
ART UNIT	**PAPER NUMBER**
1649	

MAIL DATE	DELIVERY MODE
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/577,506	YAN ET AL.	
	Examiner	Art Unit	
	STEPHEN GUCKER	1649	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *02 January 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-5* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-5* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Response to Amendment

1. The rejection under U.S.C. 112, 2nd paragraph has been withdrawn because of Applicant's amendment filed 1/2/09.

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 1-5 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Applicant indicates that support for the amendment to the claims is found in Example II on pages 28-24[sic], particularly page 29, lines 7-10. However, the specification only discloses that mice were immunized with 1-9nAc MBP (acylated N-terminal peptide comprising nine residues from myelin basic protein (MBP)) to produce symptoms of EAE, an animal model of multiple sclerosis (MS), at the same time that they were being treated with soluble RAGE (sRAGE) to intercept the interaction of ligands with the receptor. The time at which symptoms were first manifest was delayed, ~25-30 days versus ~15-20 days, following the initial immunization, comparing sRAGE and control groups, respectively. However, EAE in animals is not the equivalent of MS in humans (see Sriram et al.). Until the test mice are immunized with 1-9nAc MBP, they are perfectly healthy. In contrast, humans can only be diagnosed with MS after they display symptoms for quite some time, and there is no discernible exact beginning point in humans to definitely indicate exactly when the MS started.

This is quite unlike what is described in the specification for inducing EAE in mice, when the exact day, hour, minute, and second can be established as to when EAE began, because it is experimentally induced with an injection of 1-9nAc MBP by the practitioner. There is no adequate written description of a method of administering sRAGE to humans in order to delay the time at which symptoms are manifest in a subject afflicted with MS because what is described in the disclosure is administering sRAGE to mice at the exact moment that the EAE is being experimentally induced. By definition, a subject afflicted with MS has already experienced symptoms because that is how one knows one has MS; therefore there has already been no delay. This is a new matter rejection.

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 1-5 are rejected under 35 U.S.C. 102(b) as being anticipated by Stern et al. (US 2002/0122799 A1; “Stern") for reasons of record and the following. Stern discloses a method for treating inflammation by administering soluble receptor for advanced glycation endproducts (sRAGE) (paragraph [0032]). Multiple sclerosis (MS) is explicitly disclosed as an autoimmune disease associated with inflammation (paragraph [0035]). The many ranges of therapeutic effective amounts are disclosed in paragraphs [0098-0101], which range from about 0.2μg/day/kg body weight to about 200μg/day/kg body weight or from about 0.05μg/day/kg body weight to about 500μg/day/kg body weight or from about 0.0000001mg/day/kg body weight to about 100mg/day/kg body weight or from about 0.001mg/day/kg body weight to

about 50mg/day/kg body weight or from about 0.01mg/day/kg body weight to about 10mg/day/kg body weight. The instant claims merely recite the inherent features of sRAGE as there is no teaching in the instant disclosure that the route or method of administration distinguishes the method over the prior art.

Applicant's arguments filed 1/2/09 have been fully considered but they are not persuasive. Applicant argues that Stern does not teach a method for slowing the time at which symptoms are manifest in a subject afflicted with multiple sclerosis. However, Stern discloses exactly the same information as the instant application does; see paragraph [0374]. Mice were immunized with the N-terminal nine amino acids of MBP and were treated with sRAGE starting at the time of MBP injection. Paragraph [0379] discloses that a mouse treated with this method remained asymptomatic. This clearly meets the limitation of delayed symptomatology recited in the instant claims because the symptoms were delayed indefinitely.

6. No claim is allowed.

7. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Stephen Gucker whose telephone number is 571-272-0883. The examiner can normally be reached on Mondays through Fridays from 0930 to 1800.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Stucker, can be reached at 571-272-0911. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/S. G./

Examiner, Art Unit 1649

Stephen Gucker

April 3, 2009

/Jeffrey Stucker/

Supervisory Patent Examiner, Art Unit 1649